



## SCALING UP CAPACITY TO SUPPORT CONDUCT OF CLINICAL TRIALS IN THE EAST AFRICAN COMMUNITY (SCALE-IT)



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Dear readers

You are welcome to our first edition of the SCALE-IT Newsletter. We are thrilled to share the latest updates on our ongoing efforts to Scale up Capacity to Support the Conduct of Clinical trials in the EAC. We are proud to announce the successful development of curricula focused on; Emerging and Complex Study Designs, Clinical Trials Monitoring, and Personal Effectiveness and Leadership Skills (PELS). These materials are currently being utilized in training across the EAC partner states.

Additionally, we are pleased to highlight the successful conclusion of both the Stakeholders' Meeting, and the Training Advisory Committee (TAC) meetings, which played a crucial role in reviewing, and updating the three curricula, as well as refining the roadmap for program implementation. We extend our heartfelt gratitude to our stakeholders from the Republic of Burundi, Republic of Kenya, Republic of Rwanda, Republic of South Sudan, Republic of Tanzania and Republic of Uganda, who contributed their time and expertise to this effort.

We are excited to report the completion of training

in the Republic of Kenya and the Republic of Uganda. All participants received certificates for successful completion of the courses. A huge thanks to our dedicated trainers, trainees, and in-country investigators for making this possible.

To further enhance the harmonization of the regulatory environment within the EAC, we are working on a document summarizing the region's regulatory framework. We deeply appreciate the efforts of our investigators who shared critical regulatory documents from each country.

Finally, a big thank you to our coordinating centre team for their relentless work in driving these activities since the start. And to you, our valued readers, thank you for being part of the SCALE-IT community.

Enjoy the read!

Warm regards.

**Mathius Amperiize**

SCALE-IT project Officer

# PROJECT SUMMARY AND OBJECTIVES

The East African Community (EAC) has experienced significant increase in volume and complexity of clinical research, driven by epidemics of emerging and re-emerging infectious diseases such as HIV, Ebola and COVID-19, requiring expertise in scientific and ethical review and conduct of research and a robust and pragmatic research regulatory framework.

Overall goal: We aim to strengthen scientific and ethics capacity in the EAC for high quality research review, conduct and oversight, at international standards.

Specific objectives

- To train National Research Regulatory Authority (NRRA) personnel, Research Ethics Committee (REC) members, researchers and clinicians on scientific and ethics review and conduct of research with emerging and complex study designs including adaptive platform trials
- To train NRRA personnel and REC members on oversight, monitoring and pharmacovigilance of clinical trials
- To train NRRA personnel, REC and research administrators on personal effectiveness and leadership skills to manage the increasingly complex research processes.

## Methods:

The project is being implemented within a consortium of research scientists from the six partner states collaborating with the EU partner, with the East African Health Research Commission as the strong nucleus for coordination and dissemination of results. This project is funded by the Global Health EDCTP3 Joint Undertaking, Global Health EDCTP3, (Grant Number; 101103332), and hosted at the Infectious Diseases Institute (IDI), where within a previous NIH funded program (5G11 TW011309-01) we built capacity for REC members, researchers and REC administrators for 7 RECs in Uganda, which resulted into significant improvement in knowledge among REC members, PELS among REC and research administrators, with resultant improvement in quality and turnaround time of research protocol review and researcher satisfaction.



# Remarks from PI

Dear readers

I am very delighted to share our first newsletter highlighting the SCALE-IT project goals and progress. Research is key for societal benefit, and should be facilitated by a robust regulatory framework that promotes good science and ethics while minimising risks to research participants. Researchers must follow research principles of autonomy, beneficence, non-maleficence, and justice. Additionally, researchers should ensure scientific validity, social and clinical value, fair subject selection, favourable risk benefit ratio, informed consent and respect for individuals.

Research Ethics Committees are responsible for protecting the safety and welfare of human research participants by providing an independent evaluation of proposed research that ensures it is planned and conducted in accordance with the applicable ethical principles, standards and regulations. National Research Regulatory Agencies provide the final regulatory approval and registration of research involving humans as research participants to ensure their safety and integrity in accordance with national and international regulatory standards.

The overall goal of the SCALE-IT project is to strengthen Research Ethics Committees in the East African Community for high quality research protocol review and oversight. We aim to train National Research Regulatory Authority personnel, Research Ethics Committee members, researchers and clinicians on scientific and ethics review and conduct of research with emerging and complex study designs including adaptive platform trials, to train Research Regulatory Authority personnel and Research Ethics Committee members on oversight, monitoring and pharmacovigilance of clinical trials, and to train Research Regulatory Authority personnel, administrators of Research Ethics Committees and research projects on personal effectiveness and leadership skills (PELs), to manage the increasingly complex research processes.

We are implementing the project within a consortium of six EAC partner states the Republic of Burundi, Republic of Kenya, Republic of Rwanda, Republic of South Sudan, Republic of Tanzania and Republic of Uganda. The project is hosted at the Infectious Diseases Institute in Kampala, in partnership with Kenya Medical Research Institute, collaborating with our EU partner, EPICENTER, and the East African Health Research Commission (EAHRC).

We are glad with the positive response from the partner states so far and will soon complete the training. We look forward to an improved research review and oversight process in the EAC!

I wish to acknowledge the Global Health EDCTP3 Joint Undertaking, Global Health EDCTP3, (Grant Number; 101103332) for supporting this work.

Sincerely,  
**Prof Pauline Byakika-Kibwika**  
Principal Investigator  
SCALE-IT

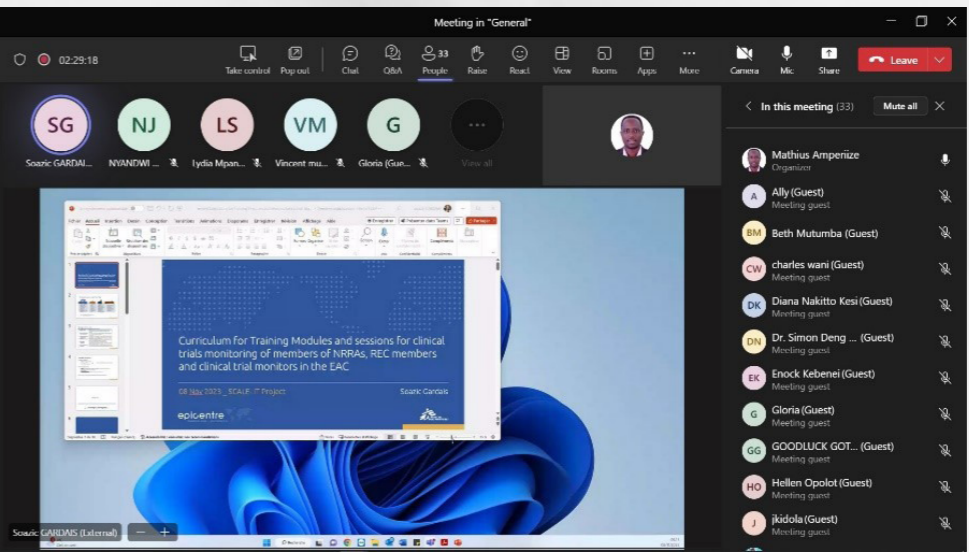


Prof Pauline Byakika Project PI delivering opening remarks at the training in Uganda

# PROGRAM UPDATES

## Stakeholder's meeting

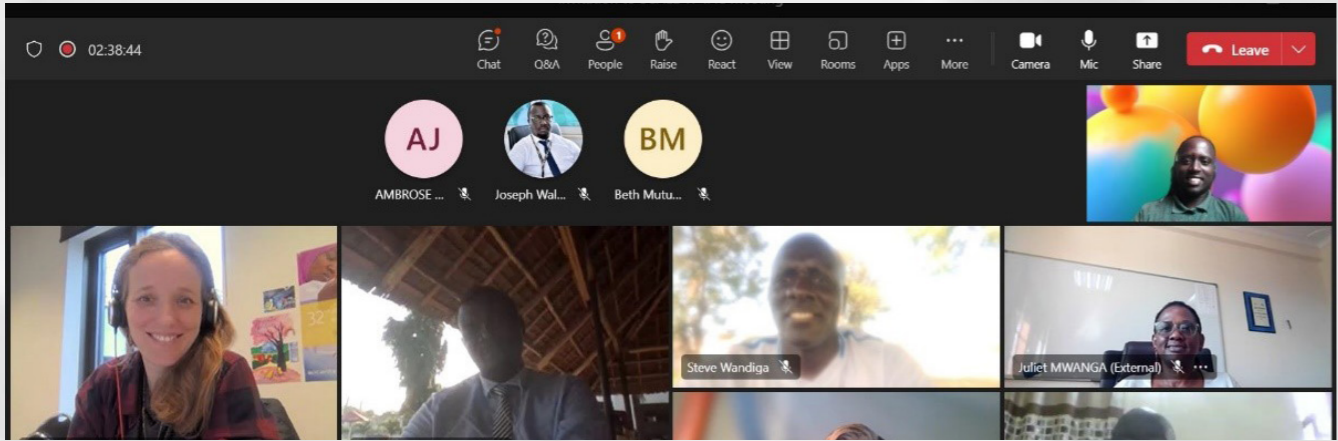
We held a successful online stakeholders meeting on 08/11/2023 that comprised of over 35 members from East African community partner states. The stakeholders were from different fields including; REC and NRRA members, researchers, and clinicians. The members were nominated by the investigators from each of the six EAC partner states. The meeting involved highlighting the project overview, and presentation of the three curricula. From each country, a stakeholder representative made a presentation summary on the regulatory process in their country. This ensured a more elaborate discussion on how the three curricula could be improved and how the project could be implemented in the three countries. Insights from this meeting guided the update of the curricula on areas of greatest need.



Soazic Presenting the curriculum on Clinical trial Monitoring to Stakeholders

### Training Advisory Committee (TAC) Meeting

On 19/12/2023 a team of seven TAC members, and all Investigators held our first successful online meeting. TAC members were mainly nominated to offer guidance about the implementation process of the project, and to provide feedback after the review of the three curricula. The meeting also saw the nomination of TAC chair and secretary who would always be in charge of these meetings that happen twice a year. Feedback from this meeting was fundamental in updating the three curricula and providing a clear strategy for the training implementation activities.



Group Photo after the online TAC meeting with the members

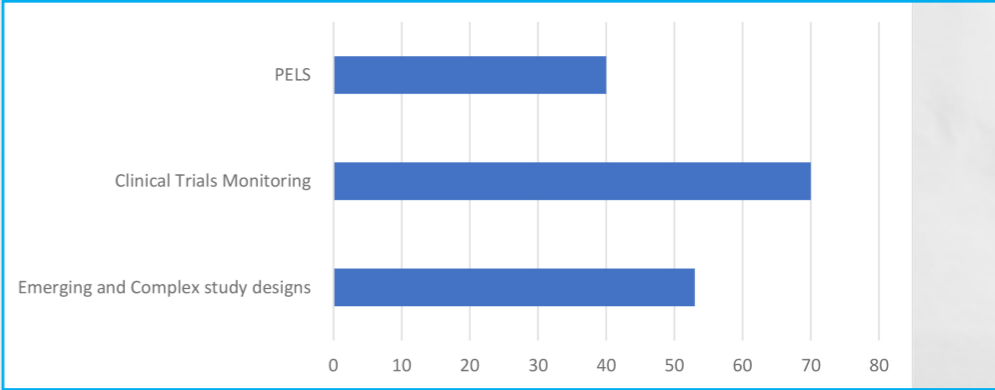
### Physical and online training in Uganda completed: overall numbers for the three courses

We held a successful training of 165 trainees on emerging and complex Study designs from 12<sup>th</sup> – 14<sup>th</sup> Feb 2024, Clinical trials monitoring from 19<sup>th</sup> – 21<sup>st</sup> Feb and PELS from April to May 2024. Participants were invited from all over the country from different institutions including RECS, NRRAs, Research institutions, health facilities and Universities. Trainees included; REC and NRRRA members, researchers, clinicians, REC and project administrators and clinical trials monitors. The trainers were carefully nominated based on their areas of expertise. The content was delivered through lectures, case studies and role plays. Participants were also enrolled via the IDI e-learning platform, and they will continue to have access for three years to ensure CPD. At the end of each course, participants who passed with the pass mark in the pre-test and post-test qualified with the certificate of course completion.



Trainees attending a session on study designs

### Number of trainees per course in Uganda



Dr Nankabirwa delivering a module

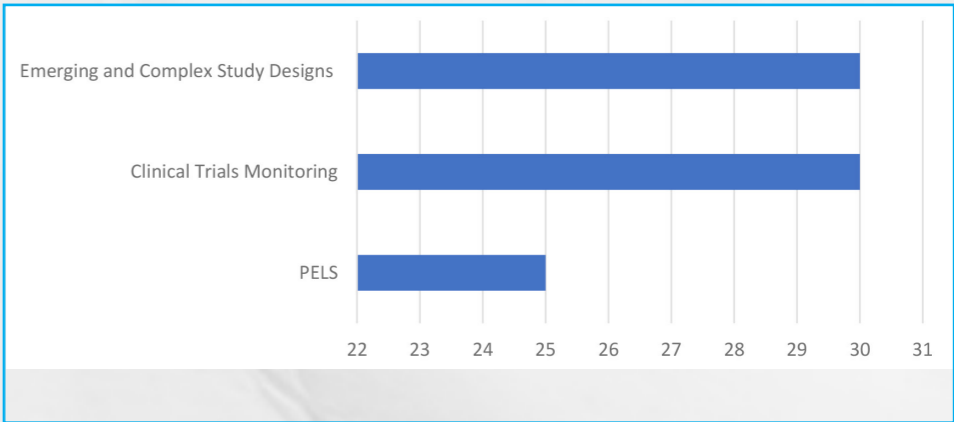


PELS trainees doing a group assignments

### Physical and online training in Kenya completed: overall numbers for the three courses

An insightful blended physical and online training of 85 trainees was completed from June to July at Kenya Medical Research Institute (KEMRI) for the three courses. Trainees comprised of REC, and NRRRA members, researchers, clinicians, clinical trial monitors and project administrators. Trainees, completed pre and post-test to evaluate knowledge shift. All trainees qualified for certification.

### Number of Trainees that attended the training

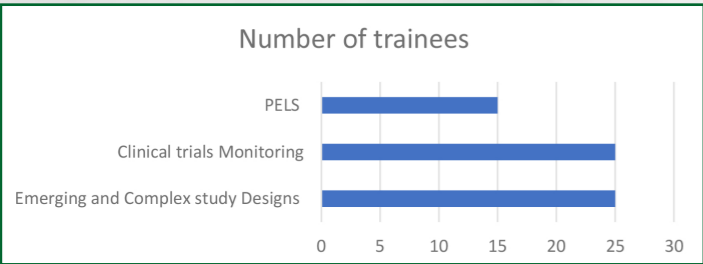




Trainees in one of the sessions at KEMRI



Dr Martin Ag DG giving opening remarks



Trainees that enrolled for the three courses

### Physical training in Rwanda Completed: Overall numbers for the three courses

From 19<sup>th</sup> to 23<sup>rd</sup> Aug 2024, we completed a successful physical training on emerging and complex study designs, clinical trials monitoring, and PELS. This was an impactful one-week training that was held at Sainte Famille Hotel Kigali Rwanda attended by over 65 trainees. Trainees were also enrolled on the online version where they completed pre-test. The training will close off in the next 4 weeks after four weeks of self-paced online and final virtual sessions and certification.



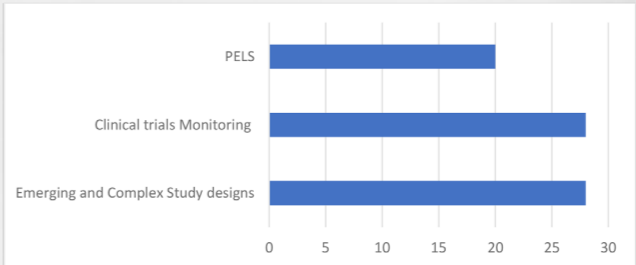
Dr Vincent Mutabazi Co-I giving opening remarks



Dr. Lydia the PELS trainer delivering a session

### Physical training in Burundi completed: Overall numbers for the three courses

The SCALE-IT training that took place at the University of Burundi from 12<sup>th</sup> to 16<sup>th</sup> Aug 2024 attracted 76 trainees. The insightful training was launched by the East African Health Research Commission (EAHRC) representative Dr Fabian. Since the courses are held in a blended manner, participants were also enrolled on the online version of the course where they will undergo online self-paced learning for 4 weeks, and then complete the courses with final virtual sessions.



Trainees that enrolled for the three courses in Burundi



Dr. Tatien Delivering a module



Group Photo for the trainees

### Oral presentation of SCALE-IT progress results; Uganda Society of Health Scientists Conference (USHS)

As part of the mandate to share our results with the stakeholders, we made a conference presentation at the recently concluded Uganda Society of Health Scientists annual conference that took place from 1-2 Aug 2024. Amidst over 150 attendees including researchers, policy makers, our project Officer, Mathius Amperiize made an insightful presentation that highlighted the current progress of the project activities.



Mathius Amperiize, Project Officer delivering an oral Conference Presentation

# SPOTLIGHT

## Success stories from Investigators

01



*"The SCALE-IT project was an opportunity for members of IRBs and other researchers to acquire the latest skills in research protocol evaluation, ethical conduct of research, complex study designs and study monitoring. This training has significantly enhanced the capacity to review and oversee complex research studies in Rwanda. Researchers are now equipped with skills to conduct and evaluate high-quality, ethically compliant research, promoting scientific integrity and growing the research ecosystem in Rwanda"*

**Dr Vincent Mutabazi, Co-I, and MOH staff Rwanda**

02

*"SCALE-IT project has provided a road map for capacity building initiatives for research regulatory teams across the Sub-Sahara Africa. It has created a network of ethicists, trainers and regulatory representatives. Due to these network and initiatives undertaken, the East African Community in a few years will be propelled to a centre of excellence in research regulation. As a Co-Investigator on the project, I greatly appreciate of the one-of-a-kind training in research management, and leadership which has increased management and communication skills of the research administrators who are lch pin of the Research Ethics Committee administrative processes and procedures. I want to express my heartfelt gratitude of the leadership and consortium support in the execution of this grant project, I am excited about the impact we are making together"*

**Beth Mutumba, Co-I and UNCST staff, Uganda**



03



*"Oversight of research involving humans as research participants in Uganda is a two-tier process which starts at the institutional level by Research Ethics Committees (RECs) and second at the national level by the UNCST. The UNCST is happy to have partnered with the SCALE-IT Project which provided the trainings that were profound, demonstrating aspects of the research processes, responsible research practices and compliance with both local and international standards that not only protects research participants but also to enhance the quality and credibility of the research in the country. It is our wish that the skills attained during the training are impactful"*

**Hellen Opolot, SCALE-IT Co-I & Assistant Executive Secretary-UNCST, Uganda**

## Success stories from trainees

04



*"The Scale-IT program has been a transformative experience for my career, marking one of the most significant professional developments of 2024. This training provided me with invaluable tools and opportunities that have significantly enhanced both my work and personal growth. A pivotal aspect of Scale-IT was the introduction of the Follow-Up and Follow Through (FUFT) strategy. This approach, highlighted as a best practice for enhancing customer experience in administrative roles, has proven to be remarkably effective. By diligently applying FUFT into my daily*

*work, I have noticed a great improvement in my interactions and the overall satisfaction of those I serve. More so, Scale-IT has facilitated connections with several key individuals who have become friends and writing buddies. One of the most notable outcomes of these relationships was my opportunity to write and present my first abstract on Social Behavioural Change. This abstract was selected for presentation at the Social Behavioural Change Summit in July 2024, a milestone that underscored the impact of Scale-IT in advancing my personal growth. Additionally, Scale-IT opened doors to international training and courses. I was recently accepted into a three-month leadership course at the University of Washington, an experience that promises to further enrich my leadership skills and professional acumen. Overall, the Scale-IT program has been instrumental in my career development. The skills and opportunities it has provided are not only enhancing my current work but also paving the way for future growth and achievements. I am confident that the benefits of Scale-IT will continue to unfold"*

**Patience Kamarunga, IDI. Trainee Uganda**

05



*"The SCALE-IT trainings had a variety of trainers from the various sectors in clinical research and this made it a worthwhile experience as presentations were interspaced with experiences in their practice. It also gathered an array of regulators and each explained their role in the clinical trial approval processes.*

*The training emphasized the need for an expedited review of protocols in the event of an emergency and this required a collaborative approach amongst all regulators as well as joint reviews as a way of reducing the approval timelines"*

**Marvin Bulera, NDA staff. Trainee Uganda**

06



"The expert trainers, and engaging presentations significantly enhanced my understanding of the content material. The dedication in advancing our knowledge

was highly valued. I feel more confident in reviewing clinical trials applications. With some of the complex and emerging study designs that I covered such as stepped wedged trial design, I will not shy away from reviewing any protocol submitted. Thank you"

**Joyce Batera, NDA Staff- Trainee Uganda**

07



"Attending the SCALE-IT training specifically on emerging, and complex study designs and clinical trial monitoring was incredibly beneficial. These sessions equipped me with advanced knowledge in managing

clinical trials efficiently, especially in adapting to complex study designs. The hands-on approach strengthened my understanding of regulatory requirements, trial protocols, and data management. This knowledge not only improved my personal skills but it also made the team more adept at precisely managing clinical trials and producing outstanding research results"

**Miriam Chelangat, Trainee Kenya, KEMRI staff. Kenya**

08



"The SCALE-IT trainings were incredibly insightful, fostering both personal and professional growth. They provided a comprehensive understanding of cutting-edge tools and strategies, which significantly enhanced my approach to problem-solving. The collaborative nature of the sessions helped our team improve in terms of communication and efficiency. Overall, the program empowered us with practical skills to tackle complex challenges in a more innovative way"

**Angel Hilda, Trainee Rwanda**

09



"My experience with the SCALE-IT program was incredible. I now have a much clearer understanding of the step-by-step process of drug discovery, which I found truly fascinating. It was eye-opening to learn about the rigorous journey and the time it takes to bring a drug to market. I never imagined how long and challenging the process was until SCALE-IT made it clear"

**RUGIRA Yves Robert, Trainee Rwanda**

10



"As a woman researcher, and the team that took part in the SCALE- IT training, we are equipped with the knowledge, skills and attitudes relating to personal effectiveness and Leadership that will enable us to work more effectively and overcome the difficulties associated with stakeholder relations. Stakeholder categories, and leadership are essential for improvement. The concepts we have learned have built us and continue to build us up in our day- to - day achievement"

**Alice NDAYIRUKIYE, Trainee Burundi**

### Meet our entire team from the six EAC countries

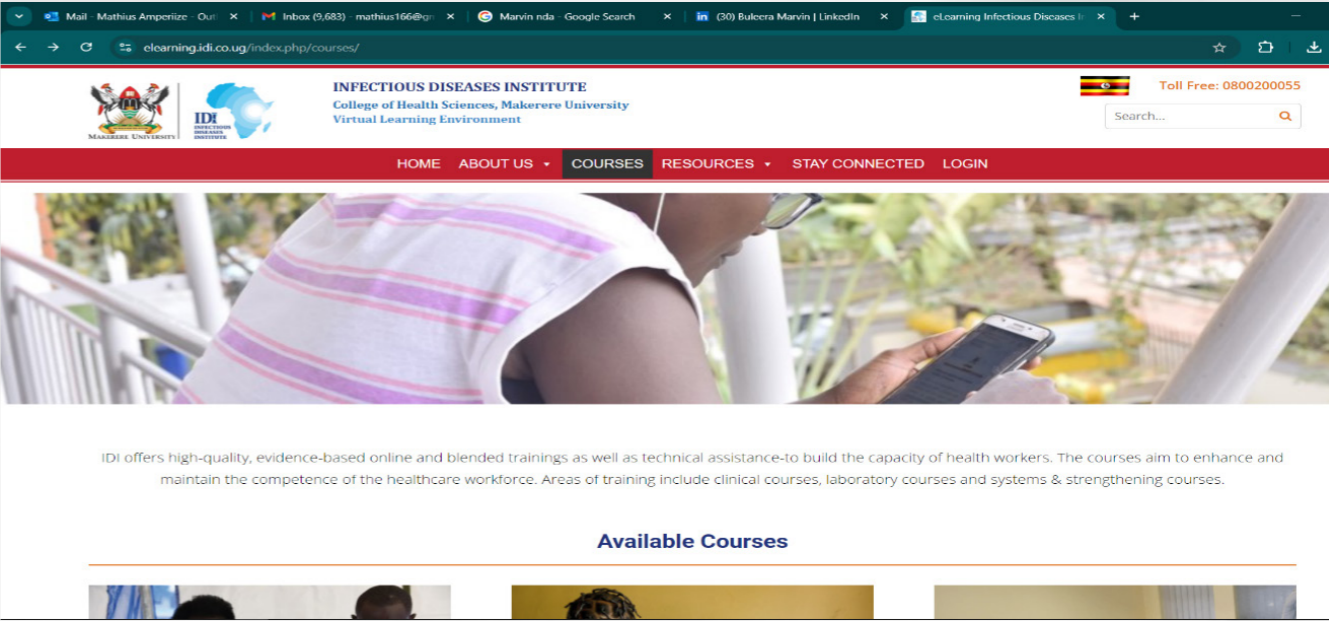
Name	Role	Institution	Country
Prof Pauline Byakika Kibwika	Scientific lead/ Principal Investigator	Infectious Diseases Institute	Uganda
Mathius Amperiize	Project Officer	Infectious Diseases Institute	Uganda
Belinda Twesigye	Project Assistant	Infectious Diseases Institute	Uganda
Immaculate Namutebi	Senior Grants Manager	Infectious Diseases Institute	Uganda
Paul Gonza	Senior Research Manager	Infectious Diseases Institute	Uganda
Linda Namara	E-Learning Team Specialist	Infectious Diseases Institute	Uganda
Kenneth Mulindwa	Communications specialist	Infectious Diseases Institute	Uganda
Dr Steve Wandiga	Co-Investigator	Kenya Medical Research Institute	Kenya
Hellen Opolot	Co-Investigator	Uganda National Council of Science and Technology	Uganda

Name	Role	Institution	Country
Soazic Gardais	Co-Investigator	EPICENTRE	France
Ainembabazi Provia	Co-Investigator	Infectious Diseases Institute	Uganda
Arinaitwe Joseph Walter	Co-Investigator	Infectious Diseases Institute	Uganda
Dr. Stephen Okoboi	Co-Investigator	Infectious Diseases Institute	Uganda
Dr. Barbara Castelnovo	Co-Investigator	Infectious Diseases Institute	Uganda
Dr. Ndagire Byomire Helen	Co-Investigator	Uganda National Drug Authority	Uganda
Dr. Novat Twungubumwe	Co-Investigator	East African Health Research Commission	Burundi
Beth Mutumba	Co-Investigator	Uganda National Council of Science and Technology	Uganda
Dr. Jeremiah Kidola Lunyalura	Co-Investigator	National Institute for Medical Research, Tanzania	Tanzania
Dr. Ramadhan Nyandwi	Co-Investigator	University of Burundi	Burundi
Dr. Rosalind Parkes Ratanshi	Co-Investigator	Infectious Diseases Institute	Uganda
Dr. Lina Sara Mathew	Co-Investigator	Bahr El Ghazal, University South Sudan	South Sudan

WHAT IS COMING UP !

Ongoing online training for Burundi and Rwanda trainees

Following a successful physical training, trainees are undergoing an online self paced learning via the IDI E-learning platform for 4 weeks and will complete with virtual sessions thereafter. Interestingly, trainees also engaged on online discussions during the 4 weeks through well-coordinated WhatsApp groups, and via the e-learning platform. This consequently enhances their learning



Interface of IDI E-learning platform

Training in Tanzania and South Sudan

Following completion of pieces of training in 4 countries, we are currently holding preparatory meetings with the Co-Investigators in Tanzania and South Sudan for our Upcoming training in the month of October and November. We expect to attract over 155 trainees from both countries. We can't wait to engage with a team of REC, and NRRRA members, researchers, clinical trial monitors, and project administrators as we strengthen scientific and regulatory capacity for high quality research review, conduct and oversight at international standards

Summary of regulatory structure in EAC document completion

In order to harmonize the understanding of the regulatory environment in EAC, the team is combining efforts to develop a document that summarises this process. This will be key in offering knowledge, and guidance to researchers carrying out different research activities within the EAC partner states.

## Drafting of training manuscripts for the three courses

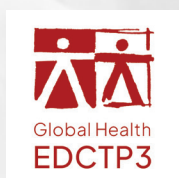
We aim to continue to disseminate our project results to a wider environment through publications. Our team is working on different manuscripts for the three courses which will be submitted in the peer reviewed journals by end of the year.

This will be a great milestone towards our efforts to scale-up capacity to support conduct of clinical trials in EAC

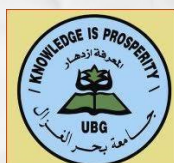
## Conference oral presentation: Makerere University Bioethics Conference

We believe that by continuously disseminating our results, we can contribute tremendously to the improvement in the conduct of clinical trials in EAC. We are therefore excited to notify our readers that our abstract was accepted at the upcoming Bioethics conference slated to happen in November.

## FUNDERS AND PARTNERS



**epicentre**  
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***This project is funded by the Global Health EDCTP3 Joint Undertaking, Global Health EDCTP3, (Grant Number; 101103332)***